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10/788,787

02/27/2004

Jan Peter Sternby

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PEARNE & GORDON LLP
1801 EAST 9TH STREET
SUITE 1200
CLEVELAND, OH 44114-3108

EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/788,787 | Applicant(s) STERNBY ET AL. |
| | Examiner LESLIE R. DEAK | Art Unit 3761 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,7-19,22,29 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,7-19,22,29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 4, 7-13, 22, 29, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,830,365 to Schneditz in view of US 2,703,586 to Asker.

In the specification and figures, Schneditz discloses the apparatus substantially as claimed by applicant. With regard to claims 29 and 11, Schneditz discloses an extracorporeal circuit 2 with a switch valve 14 comprising inlets 15, 15' and outlets 16, 16', dialyzer 3 with blood compartment 5 and blood compartment inlet and outlet connectors 5', 5". Schneditz discloses that the device is connected to arterial and venous sides of a fistula, but does not specifically disclose the use of needles. However, the use of needles to gain access to patient blood is well-known in the art and does not represent a patentable improvement over the Schneditz device. The dialysis compartment 4 of the apparatus comprises inlet and outlet dialysate lines (see FIG 1). The switch is operable to reverse blood flow among the openings in the apparatus (with monitors and calculating means) in order to measure a variable in the dialysate when the flow is in the normal condition and in the reversed condition (see column 9, line 52 to column 10, line 50).

Schneditz does not disclose that the switch 14 comprises a pivotable member with a blood-impervious partition that extends across the entire diameter of the chamber with a width less than that of the width of each opening in the valve. Asker discloses a fluid flow valve comprising a valve body 10 with ports 12, 14, 16, 18 and a chamber 22. The valve comprises a rotor element 36 which is pivotable about shaft 34. The rotor element 36 comprises a rotor vane 40 and sealing elements 50, 52 that seal the vane radially at each side against the cylindrical walls of the chamber (see column 2, lines 18-80, FIGS 2, 4). The vane as illustrated by Asker is narrower than the width of the openings (see FIG 2). The apparatus provides for improved sealing for controlling fluid flow through the valve without leakage (see column 1, lines 15-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the narrow-vaned sealing valve disclosed by Asker for the switch valve in the extracorporeal loop disclosed by Schnell in order to prevent leakage in the valve, as taught by Asker.

With regard to claim 4, Asker illustrates that the valve member is narrower than the width of the valve openings, which allows the valve member to be arranged in a position in which all four openings are interconnected, as claimed by applicant. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the narrow-vaned sealing valve disclosed by Asker for the switch valve in the extracorporeal loop disclosed by Schnell in order to prevent leakage in the valve, as taught by Asker.

With regard to claims 7-8 and 36, Asker illustrates that the valve member pivots to various positions within the valve chamber, meeting the claim limitations that the member is capable of being pivoted into the claimed positions. With regard to claims 7 and 8, examiner considers applicant's recitation with regard to the positioning of the valve to be a recitation of the functional operation of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the valve disclosed by Asker is capable of rotating and opening and closing passages as claimed by applicant, thereby meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the narrow-vented sealing valve disclosed by Asker for the switch valve in the extracorporeal loop disclosed by Schnell in order to prevent leakage in the valve, as taught by Asker.

With regard to claims 9-10, Asker illustrates a cylindrical valve in which the openings are spaced 90 degrees relative to each other around the chamber (see FIG 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the narrow-vented sealing valve disclosed by Asker for the switch valve in the extracorporeal loop disclosed by Schnell in order to prevent leakage in the valve, as taught by Asker.

With regard to claims 12-13, Asker illustrates a valve member that forms a partition between two semicircular valve chamber portions. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute

Art Unit: 3761

the narrow-ported sealing valve disclosed by Asker for the switch valve in the extracorporeal loop disclosed by Schnell in order to prevent leakage in the valve, as taught by Asker.

With regard to claims 31-33, applicant recites the measuring and calculating steps of the monitor, which is considered by the examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the controller and monitor disclosed by Schneditz is capable of being programmed to perform all the tasks claimed by applicant. With regard to claim 31, Schneditz discloses that the apparatus monitors the concentration of an indicator solution when the blood flow is in the normal position and the reversed position (see column 8, lines 48-60). With regard to claim 32, Schneditz discloses an alternate equation for calculating the blood flow in the access (see Eq 5). With regard to claim 33, Schneditz discloses the collection of the variables manipulated by applicant, indicating that the device may be programmed to manipulate the variables in the manner claimed by applicant.

With regard to claims 34 and 35, Schneditz discloses that the indicator solution may comprise dextrose (which is known in the art to contain glucose) or an isotonic saline solution (which contains Na and Cl) (see column 4, lines 55-60, column 5, lines 40-55).

Art Unit: 3761

3. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,830,365 to Schneditz in view of US 2,703,586 to Asker, further in view of US 5,443,453 to Walker et al.

With regard to claim 14, Schneditz and Asker disclose the device substantially as claimed by applicant (see rejection above) with the exception of a wing projection from the valve. Walker discloses a multi-way valve that has a rotatable valve member 13 within body 11, the rotation of which opens and closes various fluid paths (see column 3, lines 39-62). The valve member comprises handle 12 that extends outside the valve chamber for visual identification of valve position (see column 1, lines 50-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a handle or wing 12 as disclosed by Walker to the extracorporeal system with valve disclosed by Schneditz and Asker, in order to provide a visual and tactile indication of the valve position, as taught by Walker (see column 1, lines 50-60).

With regard to claims 15 and 16, Schneditz and Asker disclose the device substantially as claimed by applicant with the exception of a shoulder and a groove to control movement of the valve. Walker specifically discloses that the valve comprises a shoulder 28 the body that interacts with shoulder 27 on the stem to control movement of the valve (see FIG 3, column 4, lines 36-39). Though Walker does not specifically disclose a groove, the absence of material that allows the rotation of the valve to the point of shoulder 27 is considered by the examiner to correspond to applicant's claimed groove, meeting the limitations of the claims. Therefore, it would have been obvious to

Art Unit: 3761

one having ordinary skill in the art at the time the invention was made to add a shoulder and a groove as disclosed by Walker to the extracorporeal system with valve disclosed by Schneditz and Asker in order to prevent movement of the valve beyond a certain prescribed position, as taught by Walker (see column 4, lines 36-39).

4. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,830,365 to Schneditz in view of US 2,703,586 to Asker in view of US 5,443,453 to Walker et al, further in view of US 4,593,717 to Levasseur.

In the specification and the figures, the cited prior art discloses the device substantially as claimed by applicant (see rejection above) with the exception of recesses that define valve positions. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another (see column 2, lines 57-67). Levasseur further discloses that the valve system comprises a detent mechanism to locate the valve stem in the proper position once a particular flow mode is selected (see column 3, lines 42-64). The detent mechanism comprises a number of recesses 70 that cooperate with slot or groove 76. When the valve stem is in the proper position, rod or shoulder 72 drops into the corresponding recess 70 to maintain the valve in the proper position until the operator selects another flow mode. Therefore, it would have been obvious to add the detent mechanism with recesses as disclosed by Levasseur to the valve with groove and shoulder as disclosed by the cited prior art in order to maintain the valve in the proper position according to the selected flow mode, as taught by Levasseur (see column 3, lines 42-64).

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,830,365 to Schneditz in view of US 2,703,586 to Asker, further in view of US 4,593,717 to Levasseur.

In the specification and figures, Schneditz and Asker disclose the device substantially as claimed by applicant (see rejection above) with the exception of the non-symmetrical position of the valve openings and connectors. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another in a non-90-degree configuration (see column 2, lines 57-67). Levasseur specifically discloses that entrapment of bubbles in a 90-degree flow conduit is more likely than that in an angled conduit (see column 1, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide flow passages at a less than 90-degree angle as disclosed by Levasseur in the valve assembly disclosed by Schneditz and Asker, in order to prevent bubble entrapment, as taught by Levasseur (see column 1, lines 20-25).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 3761

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 4, 7-13, 22, 29, and 31-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 15, 17, 20, 21, and 26 of U.S. Patent No. 6,726,647 to Sternby in view of US 2,703,586 to Asker.

Although the conflicting claims in the Sternby '647 patent and the instant application are not identical, they are not patentably distinct from each other because the instantly claimed invention claims the same elements of a dialysis system with a valve, including the monitoring and calculating means recited in the parent patent. This double-patenting rejection is not made based on a restriction requirement, since the originally prosecuted claims in the instant case (and those restricted out in the parent case) were drawn to a dialysis system valve without the newly claimed monitor and calculating means.

With regard to claims 29 and 11, Sternby '647 does not disclose that the switch 14 comprises a pivotable member with a blood-impervious partition that extends across the entire diameter of the chamber with a width less than that of the width of each opening in the valve. Asker discloses a fluid flow valve comprising a valve body 10 with ports 12, 14, 16, 18 and a chamber 22. The valve comprises a rotor element 36 which is pivotable about shaft 34. The rotor element 36 comprises a rotor vane 40 and sealing elements 50, 52 that seal the vane radially at each side against the cylindrical walls of the chamber (see column 2, lines 18-80, FIGS 2, 4). The vane as illustrated by Asker is narrower than the width of the openings (see FIG 2). The apparatus provides for improved sealing for controlling fluid flow through the valve without leakage (see column 1, lines 15-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the narrow-vaned sealing valve disclosed by Asker for the switch valve in the extracorporeal loop disclosed by Schnell in order to prevent leakage in the valve, as taught by Asker.

With regard to claim 4, Asker illustrates that the valve member is narrower than the width of the valve openings, which allows the valve member to be arranged in a position in which all four openings are interconnected, as claimed by applicant.

With regard to claims 7-8 and 36, Asker illustrates that the valve member pivots to various positions within the valve chamber, meeting the claim limitations that the member is capable of being pivoted into the claimed positions. With regard to claims 7 and 8, examiner considers applicant's recitation with regard to the positioning of the valve to be a recitation of the functional operation of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the valve disclosed by Asker is capable of rotating and opening and closing passages as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 9-10, Asker illustrates a cylindrical valve in which the openings are spaced 90 degrees relative to each other around the chamber (see FIG 5A).

With regard to claims 12-13, Asker illustrates a valve member that forms a partition between two semicircular valve chamber portions.

With regard to claims 31-35, see Sternby '647 claims 14, 15, 17, 20, and 21.

8. Claims 14-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 26 of U.S. Patent No.

Art Unit: 3761

6,726,647 to Sternby in view of US 2,703,586 to Asker, further in view of US 5,443,453 to Walker et al.

With regard to claim 14, Sternby and Asker disclose the device substantially as claimed by applicant (see rejection above) with the exception of a wing projection from the valve. Walker discloses a multi-way valve that has a rotatable valve member 13 within body 11, the rotation of which opens and closes various fluid paths (see column 3, lines 39-62). The valve member comprises handle 12 that extends outside the valve chamber for visual identification of valve position (see column 1, lines 50-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a handle or wing 12 as disclosed by Walker to the extracorporeal system with valve disclosed by Sternby and Asker, in order to provide a visual and tactile indication of the valve position, as taught by Walker (see column 1, lines 50-60).

With regard to claims 15 and 16, Sternby and Asker disclose the device substantially as claimed by applicant with the exception of a shoulder and a groove to control movement of the valve. Walker specifically discloses that the valve comprises a shoulder 28 the body that interacts with shoulder 27 on the stem to control movement of the valve (see FIG 3, column 4, lines 36-39). Though Walker does not specifically disclose a groove, the absence of material that allows the rotation of the valve to the point of shoulder 27 is considered by the examiner to correspond to applicant's claimed groove, meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a shoulder

Art Unit: 3761

and a groove as disclosed by Walker to the extracorporeal system with valve disclosed by Schneditz and Asker in order to prevent movement of the valve beyond a certain prescribed position, as taught by Walker (see column 4, lines 36-39).

9. Claims 17-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 26 of U.S. Patent No. 6,726,647 to Sternby in view of US 2,703,586 to Asker in view of US 5,443,453 to Walker et al, further in view of US 4,593,717 to Levasseur.

In the specification and the figures, the cited prior art discloses the device substantially as claimed by applicant (see rejection above) with the exception of recesses that define valve positions. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another (see column 2, lines 57-67). Levasseur further discloses that the valve system comprises a detent mechanism to locate the valve stem in the proper position once a particular flow mode is selected (see column 3, lines 42-64). The detent mechanism comprises a number of recesses 70 that cooperate with slot or groove 76. When the valve stem is in the proper position, rod or shoulder 72 drops into the corresponding recess 70 to maintain the valve in the proper position until the operator selects another flow mode. Therefore, it would have been obvious to add the detent mechanism with recesses as disclosed by Levasseur to the valve with groove and shoulder as disclosed by the cited prior art in order to maintain the valve in the proper position according to the selected flow mode, as taught by Levasseur (see column 3, lines 42-64).

10. Claim 19 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 26 of U.S. Patent No. 6,726,647 to Sternby in view of US 2,703,586 to Asker, further in view of US 4,593,717 to Levasseur.

In the specification and figures, Sternby and Asker disclose the device substantially as claimed by applicant (see rejection above) with the exception of the non-symmetrical position of the valve openings and connectors. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another in a non-90-degree configuration (see column 2, lines 57-67). Levasseur specifically discloses that entrapment of bubbles in a 90-degree flow conduit is more likely than that in an angled conduit (see column 1, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide flow passages at a less than 90-degree angle as disclosed by Levasseur in the valve assembly disclosed by Sternby and Asker, in order to prevent bubble entrapment, as taught by Levasseur (see column 1, lines 20-25).

Response to Arguments

11. Applicant's arguments and amendments filed 21 January 2008 have been entered and considered.

12. While applicant's amendments did, in fact, overcome the rejection over Tanaka as discussed in the 15 January 2008 interview, the amendments do not appear to overcome the disclosure of the newly discovered Asker reference, applied above, which

provides a pivotable valve member with a sealing partition and other elements that render the instantly claimed invention unpatentable over the cited combinations.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Patent Examiner
Art Unit 3761
3 March 2008